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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/701,293

11/03/2003

Edward Nowak

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EXAMINER

SHEIKH, HUMERA N

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

06/19/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/701,293	Applicant(s) NOWAK ET AL.	
	Examiner Humera N. Sheikh	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of the Application

The Non-Final Office Action filed 05/12/09 has been vacated. The following Office Action is given.

Receipt of the Substitute Appeal Brief filed 01/13/09 is acknowledged.

Applicant's request for reconsideration of the finality of the rejection of the last Office action (filed 01/22/08) is persuasive and, therefore, the finality of that action is withdrawn.

In view of the Appeal Brief, PROSECUTION IS HEREBY REOPENED.

Claims 15-52 are pending in this action. Claims 1-14 have previously been cancelled.

Claims 15-52 are rejected.

* * * * *

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15 and 28-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 recites the limitation, "...the capsule including a dividing wall or septum...". The term "*including*" renders the claim indefinite because it is unclear as to what additional components or features, besides those instantly recited, are required in the capsule. It is suggested that the term "including" be replaced with the term "comprising" to better define the components/features of the delivery capsule.

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Claims 28-42 recite the limitation, "...wherein said at least two chambers are designed to release their contents under similar circumstances (claims 28-34) and under different circumstances (claims 35-42)". The phrase renders the claims indefinite because it is unclear and confusing as to what the particular "similar circumstances" and "different circumstances" are, under which the two chambers release their contents. The claim limitation is entirely vague and the specific metes and bounds of the limitation cannot be ascertained given the current claim language presented. No specific circumstances have been recited which would establish the conditions under which the contents of the chambers should be released.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 15-45 and 51-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong *et al.* (hereinafter “Wong”) (U.S. Patent No. 5,499,979).

Wong (‘979) teaches a drug delivery system comprising a dispenser which is capable of delivering a plurality of drugs in any desired pattern or profile. The dispenser comprises: (a) a housing; (b) an inlet in the housing; (c) an outlet in the housing; (d) a plurality of longitudinally aligned layers in the housing comprising; (e) a drug formulation layer, which erodes over time when moved by gas pressure to a contacting fluid at the outlet of the dispenser; (f) an inert formulation layer in contacting arrangement with the drug formulation layer, which inert formulation layer is a means for enabling the drug formulation layer to be delivered as a unit dose over time to the environment; and (g) a gas-generating formulation layer in the housing for generating a gas pressure for moving the drug formulation layer out of the dispenser, said gas-generating formulation layer positioned at the inlet in the housing for receiving fluid that enters the dispenser (see Abstract; Claim 1; column 18, line 30 - col. 19, line 12).

Wong teaches that the dispenser is used to dispense delivery layers containing the same or different active agents (col. 2, lines 13-15); (col. 3, lines 17-25). The dispenser contains a rigid housing, a plurality of movable drug layers filling a portion of the housing, a fluid activated driving member for displacing the drug layers and a drug outlet means (col. 2, lines 20-25).

The figures demonstrate various embodiments of the invention. Figure 11, for instance, demonstrates a dispenser having two walled sections (a first and second walled section). The system (154) comprises a housing member (156) comprising a dispensing component identified by first wall section (158) and a driving component identified by second wall section (160), which surround and define an internal compartment (162), which contains a plurality of drug

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layers (164). The two walled sections 158 and 160 at receiving end 168 are close in size and they form a tight friction therebetween. Wall section 158 and wall section 160 can be telescoped completely into a closed and continuous walled position. They can also be held together by heat fusion, by an adhesive or the like (col. 14, line 30 – col. 15, line 38). Layer 174 is substantially impermeable to passage of fluid and serves to restrict passage of fluid in the expandable driving member into compartment 162 housing the drug layers. Layer 174 further operates to essentially maintain the integrity of the drug layers and driving component 172. Hence, the example illustrates a dispenser comprising a housing, which has a spacer (wall 174) whereby the wall has two opposing layers of material that can be held together by heat fusion, by an adhesive or the like. The dispenser of Wong is functionally and structurally equivalent to and meets the delivery capsule system as is instantly claimed.

Figure 13 further demonstrates two-walled sections that can be joined together by various techniques such as solvent welding, adhesive bonding, thermal welding, ultrasonic welding, spin welding, induction welding and the like (col. 15, line 57 - col. 16, line 16).

Suitable materials for forming the housing are disclosed at columns 5-9 and include for instance, cellulosic polymers, polyethylene oxide polymers, polyvinyl alcohol, natural gums and the like.

Suitable active agents for use in the dispenser are disclosed at column 6, lines 36-65.

It is noted that the instant claims recite a “delivery capsule”. While Wong does not teach a “capsule”, the particular form recited by Applicant (capsule) does not distinguish over the drug delivery system of Wong who clearly teaches a housing unit comprised of opposing walls having the same or different active ingredient, whereby the walls have a spacer or divider to maintain

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integrity of the walls. The dispenser of Wong is functionally and structurally equivalent to the capsule as claimed herein. The housing system of Wong is further made from the same materials as the capsule instantly claimed. Thus, the instant invention when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, based on the teachings of Wong.

* * * * *

Claims 15, 16, 19-43 and 51-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makiej, Jr. (hereinafter “Makiej”) (U.S. Patent No. 4,936,461).

Makiej (*461) teaches a multidose capsule for carrying multiple or graduating doses of medicinal particles, beads or liquids. The capsule includes a hard gelatin tube having a first and second end and a frangible dividing section supported by the tube, which divides the tube into first and second chambers. The frangible dividing section comprises a first wall and a second wall spaced there from. A portion of the hard gelatin tube is scored or notched to facilitate rupturing of the dividing section therealong under applied stress (col. 1, line 65 – col. 2, line 37).

The figures demonstrate various embodiments of the invention. Figure 1, for instance, illustrates a capsule (10) that includes a tube (11) having a first end (12) and second end (14) and a dividing section (16) that separates tube (11) into a first chamber (18) and a second chamber (20). The resulting capsule is thus divided into two separate chambers that can contain equal volumetric amounts of the desired medication (col. 2, line 52 – col. 4, line 7).

Figure 2 also illustrates a multidose capsule having first and second chambers for incorporating a double dose of medication whereby the doses provided by the first and second chambers need not be equivalent (col. 4, line 8 – col. 5, line 17).

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The multidose, multichambered capsule of Makiej reads on the capsule as instantly claimed. The capsule comprises two chambers separated by a first and second wall material, wherein the capsule is capable of carrying multiple or graduating doses of medicinal particles, beads or liquids. The capsule of Makiej is functionally and structurally equivalent to the delivery capsule system as instantly claimed.

* * * * *

Claims 46-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown (WO 97/35537) in view of Ueda *et al.* (EPO 0 211 079 A1).

Brown ('537) teaches capsules, a method of encapsulation and an encapsulation apparatus, wherein the capsules comprise metered doses of substances to be encapsulated within the capsule, wherein as the doses of substances are injected between the heated films, the films deform to line the indentations, forming series of pairs of opposed capsule halves containing the substance. The pairs of capsule halves are then brought together, sealed and cut, thus forming capsules containing the substance.

The method of encapsulation is characterized by supplying to an encapsulation unit, two films of like material capable of deforming elastically at least when partially solvated, and applying solvent to at least one of the films prior to encapsulation to cause partial solvation of the material surface, such that the partially solvated surface can adhere to and seal with the film material. The invention enables encapsulation-using materials other than gelatin, such as polyvinyl alcohol. Further suitable materials include alginate, hydroxypropyl methyl cellulose and polyethylene oxide, for example (see page 6, lines 5-19 and Abstract).

Brown teaches a single chamber that is not divided. Brown does not teach two separate chambers having a dividing wall or partition.

Ueda ('079) teaches a soft multi-chamber delivery capsule, process of making and an apparatus for producing the capsule, wherein the capsule consists of a covering, the inner space of which is divided into a plurality of chambers by at least one partition. The number of such chambers is usually two, and the space between the first and second coverings is divided into two chambers by a partition provided therebetween. The capsule comprises a first, second and third film, whereby the films are joined under pressure, except their respective capsule-defining portions. The chambers contain materials, such as medicine, cosmetics or food (see Abstract).

Ueda teaches a soft capsule of novel structure, which, although single, is adapted to stably enclose at least two kinds of incompatible contents, and which can be made, for example, to have one portion of rapidly soluble or intragastrically soluble properties and the other portion of prolonged release or enteric properties, or to have one portion with a rapid release action and the other portion with a delayed release action. With the multicellular soft capsule, different contents can be enclosed in the different cells (page 2, lines 15-23).

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate multi-compartments comprising a partition as taught by Ueda within the capsules of Brown. One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Ueda teaches a soft multi-chamber delivery capsule containing a partition, whereby the multiple compartments function to hold at least two

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components or substances that can be incompatible with each other. The expected result would be an improved multi-compartmented capsule for delivering metered doses of varied active substances.

* * * * *

Pertinent Art

Prior Art made of record and cited of interest:

Whitehead *et al.* (U.S. Patent No. 4,642,230) (02-1987)

* * * * *

Response to Arguments

Applicant's arguments see Appeal Brief, filed 01/13/09, with respect to the rejection(s) of claim(s) 15-52 under 35 U.S.C. §103(a) have been fully considered and are persuasive. Therefore, the rejections have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the Wong *et al.* (USPN 5,499,979); Makiej, Jr. (USPN 4,936,461) and Ueda *et al.* (EPO 0211079A1) references. Whitehead *et al.* (USPN 4,642,230) has been cited of interest.

Conclusion

--No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday-Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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